

## **REMARKS**

Claims 1, 2, 5, 6, 9, 12, 14, 16, 20, 23, 25, 27, 31, 32 and 45-48, as herein amended, and claims 4, 8, 17, 18, 28 and 29 as filed are pending in the application. The amendments are fully supported by the specification as filed and no new matter is introduced into the application by way of these amendments.

The grounds of rejection contained in the outstanding Office Action have been overcome in part by amendment and traversed in part by Applicants' argument herein.

Applicants have amended the specification to recite the U.S. patent number as required, and have cancelled claims 40, 41, 43 and 44 that are objected to in the Action.

### **The claims as amended are enabled by Applicants' specification.**

The pending claims stand rejected under 35 U.S.C. §112, first paragraph as being non-enabled. The rejection is based on the scope of the claims with regard to type of disease, type of bodily fluid assayed and the broad scope of the claims. Applicants have amended the claims to recite neoplastic disease in humans, wherein said neoplastic disease is associated with the expression or overexpression of one or more RNA species, and wherein the extent of expression is compared with a reference human population without neoplastic disease, and wherein the acellular fraction of blood is the bodily fluid assayed. Applicants respectfully contend that were the first to provide evidence that disease-associated RNA could be detected in blood in humans with neoplastic disease, and that they are entitled to the claimed scope since the skilled worker would not have to exercise undue experimentation in view of their disclosure.

Applicant respectfully contends that, having clarified the language recited in the pending claims with his amendment, he has traversed the asserted rejection on lack-of-enablement grounds. Applicant respectfully requests that the Examiner withdraw these grounds of rejection.

### **The claims as amended are not indefinite.**

Claims 9, 12-20, 23-29, 31, 32, 39-44, 47 and 48 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicant has amended the claims to overcome these grounds of amendment. Claims 9 and 20 have been amended to recite that they are directed to human disease and detecting RNA expression from human blood plasma or serum. Claims 31 and 32 have been

amended to recite the step of identifying a human having a neoplastic disease. Finally, claims 39 and 40-42 have been cancelled in order to expedite prosecution of the pending claims to allowance.

Applicant respectfully contends that, having clarified the language recited in the pending claims with his amendment, he has traversed the asserted rejection on indefiniteness grounds. Applicant respectfully requests that the Examiner withdraw these grounds of rejection.

**The pending claims are not anticipated by the cited art.**

Claims 39-44 stand rejected under the provisions of 35 U.S.C. §102(b) as being anticipated by the Balazs reference, and claims 42-44 are rejected under 35 U.S.C. §102(b) as being anticipated by the Datta reference. In order to pursue expeditious allowance of the remaining claims. Applicant has cancelled these claims for prosecution in a related continuing application. Applicants thus respectfully contend that these amendments overcome the asserted grounds of rejection, and respectfully solicit allowance of the pending claims.

**Applicants acknowledges the obviousness-type double patenting rejection.**

Applicant acknowledges rejection of the pending claims under the judicially-created doctrine of obviousness-type double patenting over co-owned U.S. Patent Nos. 6,329,179, 6,759,217 and 6,916,634. Applicant will file a Terminal Disclaimer to overcome this ground of rejection upon withdrawal of the remaining grounds of rejection and when the pending claims are otherwise in condition for allowance.

### **CONCLUSIONS**

Applicant believes that all grounds of rejection have been overcome by amendment, and request that the pending claims be passed to issue.

If Examiner Lu believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,  
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